

ECG - MI Novacode Serial Comparison

Data File: ecg_mi_nova_ct_pub File Date: 09/21/2007 Structure: Multiple rows per participant Population: CT participants

Participant ID

Variable # 1 Usage Notes: none

Sas Name: ID

Categories: Study: Administration Sas Label: Participant ID

Baseline ECG days since randomization

Variable # 2 Usage Notes: none

Sas Name: ECGBASEDAYS

Categories: Clinical Tests: ECG Sas Label: Baseline ECG days since randomization

Std Dev Ν Min Max Mean -36.35682 117596 -1114 129 29.79974

Baseline ECG MI novacode

Sas Name: ECGBASENOVA

group

abnormalities

5.6.2

5.7

5.8

Variable # 3 Usage Notes: Use for comparison with a follow-up ECG Novacode.

Categories: Clinical Tests: ECG Sas Label: Baseline ECG MI novacode

Values Ν % 5.0 No significant Q waves and no 82,011 69.7% significant ST-T abnormalities Q wave MI with major Q waves 0.2% 215 5.2 Q wave MI with moderate Q waves 138 0.1% and with ST-T abnormalities 5.3 Possible Q wave MI w/moderate Q 905 0.8% waves w/o ST-T abnormalities 5.4 0.5% Possible Q wave MI w/minor Q 607 waves with ST-T abnormalities 5.5 Profound ST-T abnormalities 2,087 1.8% without Q waves 5.6 Significant ST-T abnormalities 1,690 1.4% without Q waves 5.6.1 STD or TN score >= 20 in any lead 0.0%

Follow-up ECG days since randomization

Q score < 15 in all lead groups

Minor Q waves without ST-T

Minor ST-T abnormalities

Variable # 4 Usage Notes: none

Sas Name: ECGFUDAYS

Categories: Clinical Tests: ECG Sas Label: Follow-up ECG days since randomization

0

10,342

19,601

117,596

0.0%

8.8%

16.7%

Std Dev N Min Max Mean 117596 350 710.85978 3861 1788.0996

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Data File: ecg_mi_nova_ct_pub File Date: 09/21/2007 Structure: Multiple rows per participant Population: CT participants

Follow-up ECG visit type

Variable # 5 Usage Notes: none

Sas Name: ECGFUVTYP

Sas Label: Follow-up ECG visit type

Values N % Screening 0 0.0% 1 2 Semi-annual 0.5% 607 3 Annual 116,342 98.9% 0.0% Non-routine 50 597 0.5% Missing 117,596

Categories: Clinical Tests: ECG

Follow-up ECG visit year

Variable # 6 Usage Notes: none

Sas Name: ECGFUVY

Sas Label: Follow-up ECG visit year

Categories: Clinical Tests: ECG

N	Min	Max	Mean	Std Dev
116949	1	11	4.87516	1.94976

Closest to visit (follow-up ECG)

For forms entered with the same visit type and year, indicates the one closest to that visit's target date. Valid for forms entered with an annual or semi-annual visit type.

Variable # 7 Usage Notes: See Data Preparation Document.

Sas Name: ECGVCLO

Sas Label: Closest to visit (follow-up ECG)

Values Ν % 0 No 798 0.7% 99.3% 1 Yes 116,798 117,596

Categories: Clinical Tests: ECG

Expected for visit (follow-up ECG)

The ECG was expected for this visit. ECGs were expected at screening (baseline) and at years 3, 6 and 9.

Variable # 8 Usage Notes: none

Sas Name: ECGEXP

Sas Label: Expected for visit (follow-up ECG)

% **Values** Ν 2.4% 0 No 2,813 1 Yes 114,783 97.6% 117,596

Categories: Clinical Tests: ECG

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Follow-up ECG MI novacode

Variable # 9

Sas Name: ECGFUNOVA

Sas Label: Follow-up ECG MI novacode

Values		N	%
5.0	No significant Q waves and no significant ST-T abnormalities	76,084	64.7%
5.1	Q wave MI with major Q waves	318	0.3%
5.2	Q wave MI with moderate Q waves and with ST-T abnormalities	228	0.2%
5.3	Possible Q wave MI w/moderate Q waves w/o ST-T abnormalities	1,170	1.0%
5.4	Possible Q wave MI w/minor Q waves with ST-T abnormalities	1,011	0.9%
5.5	Profound ST-T abnormalities without Q waves	3,046	2.6%
5.6	Significant ST-T abnormalities without Q waves	2,108	1.8%
5.6.1	STD or TN score >= 20 in any lead group	0	0.0%
5.6.2	Q score < 15 in all lead groups	0	0.0%
5.7	Minor Q waves without ST-T abnormalities	12,805	10.9%
5.8	Minor ST-T abnormalities	20,826	17.7%
		117,596	

Usage Notes: none

Categories: Clinical Tests: ECG

Incident novacode

Variable # 10

Sas Name: ECGINCDNTNOVA

Sas Label: Incident novacode

Values		N	%
5.0	No significant Q waves and no significant ST-T abnormalities	109,832	93.4%
5.1	Q wave MI with major Q waves	48	0.0%
5.2	Q wave MI with moderate Q waves and with ST-T abnormalities	82	0.1%
5.3	Possible Q wave MI w/moderate Q waves w/o ST-T abnormalities	328	0.3%
5.4	Possible Q wave MI w/minor Q waves with ST-T abnormalities	147	0.1%
5.5	Profound ST-T abnormalities without Q waves	600	0.5%
5.6	Significant ST-T abnormalities without Q waves	3	0.0%
5.6.1	STD or TN score >= 20 in any lead group	348	0.3%
5.6.2	Q score < 15 in all lead groups	1,981	1.7%
5.7	Minor Q waves without ST-T abnormalities	4,225	3.6%
5.8	Minor ST-T abnormalities	2	0.0%
		117,596	

Usage Notes: Based on serial ECG comparison. Reference: Rautaharju, P, et

al. The Novacode criteria for classification of ECG abnormalities and their clinically significant progression and regression. J

Electrocardiol. 1998 Jul;31(3):157-187.

Categories: Clinical Tests: ECG

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Silent MI (evolving Q-wave; first occurrence)

First occurrence of an evolving Q-wave MI based on an incident Novacode of 5.1 or 5.2.

Sas Name: ECGSILNTMI

Variable # 11

Sas Label: Silent MI (evolving Q-wave; first occurrence)

% **Values** 0 No 117,476 99.9% 1 Yes 120 0.1% 117,596

Usage Notes: WHI-CCC does not count a silent MI occurring after a clinical MI.

Categories: Clinical Tests: ECG

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Possible silent MI (first occurrence)

First occurrence of a possible evolving Q-wave MI based on an incident Novacode of 5.3 or 5.4.

Usage Notes: WHI-CCC does not count a silent MI occurring after a clinical MI.

Sas Name: ECGPOSMI

Variable # 12

Sas Label: Possible silent MI (first occurrence)

Values Ν % 117,157 99.6% 0 No Yes 0.4% 439

117,596

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